

The Pregnancy and Infant Development (PRIDE) Study: Intended Study Design

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PRIDE
Study

Why This Study? (1)

- PhD project: “Medical and recreational drugs during pregnancy and congenital malformations in offspring”
 - ✓ Funded by NWO Toptalent Grant 2007
- Validity previous studies on pregnancy outcome ?
 - ✓ Retrospective data collection: recall bias
 - ✓ Exposure or outcome poorly defined
 - ✓ Timing and frequency of exposure unknown
 - ✓ No information about confounders (registries)
 - ✓ Underpowered

⇒ Large prospective study: more valid results

Why This Study? (2)

- PRIDE Study, Nijmegen / The Netherlands
 - ✓ Large study population
 - study relatively rare disorders
 - ✓ Inclusion early in pregnancy
 - close to etiologically relevant moment
 - ✓ Broad design (many determinants and outcomes)
 - from preconception care to
 - more specific information collected in subgroups

⇒ **UNIQUE COHORT IN EUROPE**

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Objectives (1)

- To evaluate the preconception, prenatal and perinatal care in the Netherlands

Example: Does preconception care have a positive effect on the health of the child?

- To describe the distribution of determinants during pregnancy and to estimate the incidences and prevalences of various outcome parameters

Example: How many women smoke during pregnancy?

Objectives (2)

- To study which factors influence the health of the (pregnant) woman and her (unborn) child

Example: What is the effect of medication use during the first trimester on the occurrence of major birth defects?

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Dutch Prenatal Care System

- Base: pregnancy and birth are natural events
vs. pregnancy and birth are a potential threat for mother and child
- Pregnant women primarily seen by midwives
- Without complications, women may choose place of delivery:
 - ✓ At home or in maternity hotel
 - ✓ Hospital, out-patient
 - ✓ Hospital, admission
- Intensive collaboration between midwives and specialists in case of complications

Midwife

Gynecologist

General Design PRIDE Study

- Prospective cohort study
- Study population:
 - ✓ 150,000 pregnant women
 - ✓ Study area: The Netherlands
- Recruiting participants:
 - ✓ Midwife practices (expectation: 80% participation)
 - ✓ Gynecologists in hospitals
 - ✓ Expectation: participation rate women: 75%
 - ✓ Total inclusion period: 2 years (2009-2010)



Data Collection: Digital Questionnaires



- Advantages:
 - ✓ Data quality is good
 - ✓ No data entry errors
 - ✓ More possibilities compared to paper-and-pencil questionnaires
 - ✓ Greater feeling of anonymity
 - ✓ Low costs; e-mail can be used for sending reminders
- Disadvantages:
 - ✓ Participants are self-selected sample
 - ✓ Problems with Internet connection may lead to non-response
 - ✓ Internet coverage and computer knowledge must be sufficient

Data Collection (1): Items Questionnaire

- Demographic characteristics and family history
- Pregnancy and pregnancy history
- General health
- Lifestyle and nutrition
- Spare time activities and living environment
- Occupation
- Preconception care
- Expectations concerning pregnancy and delivery
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page 1 of 4

Questionnaire

Personal Information

1. Your occupation:

Architect

Building Designer / Specifier

Interior Designer

Builder

Engineer

Carpenter or other Tradesman

Other

2. Your postcode:

3. Do you make most of the timber purchasing decisions for your organisation?

YES NO

Data collection (2)

- Questionnaires: first contact midwife / gynecologist
 - ✓ Preconceptional / \pm week 8 gestation
 - ✓ Study leaflet + access code
 - ✓ Digital consent form
 - ✓ Start study with first questionnaire
- Blood samples ?
 - ✓ Genetic studies
 - ✓ Exposures
- Linking with existing registries ?
- Start in 2009



Data Collection (3): Rough Time Schedule

Week	What	Content
Preconceptional	Questionnaire (1a)	General + TTP
8-10	Questionnaire (1b) Blood sample ?	General + TTP
14-15	Questionnaire (2) Questionnaire (father)	1st trimester
20	Ultrasound	
35	Questionnaire (3)	2nd + 3rd trimester
40	Birth	
½ year after birth	Questionnaire (4)	Maternal and child health
.....	Questionnaire	

Preconception Care in the PRIDE Study

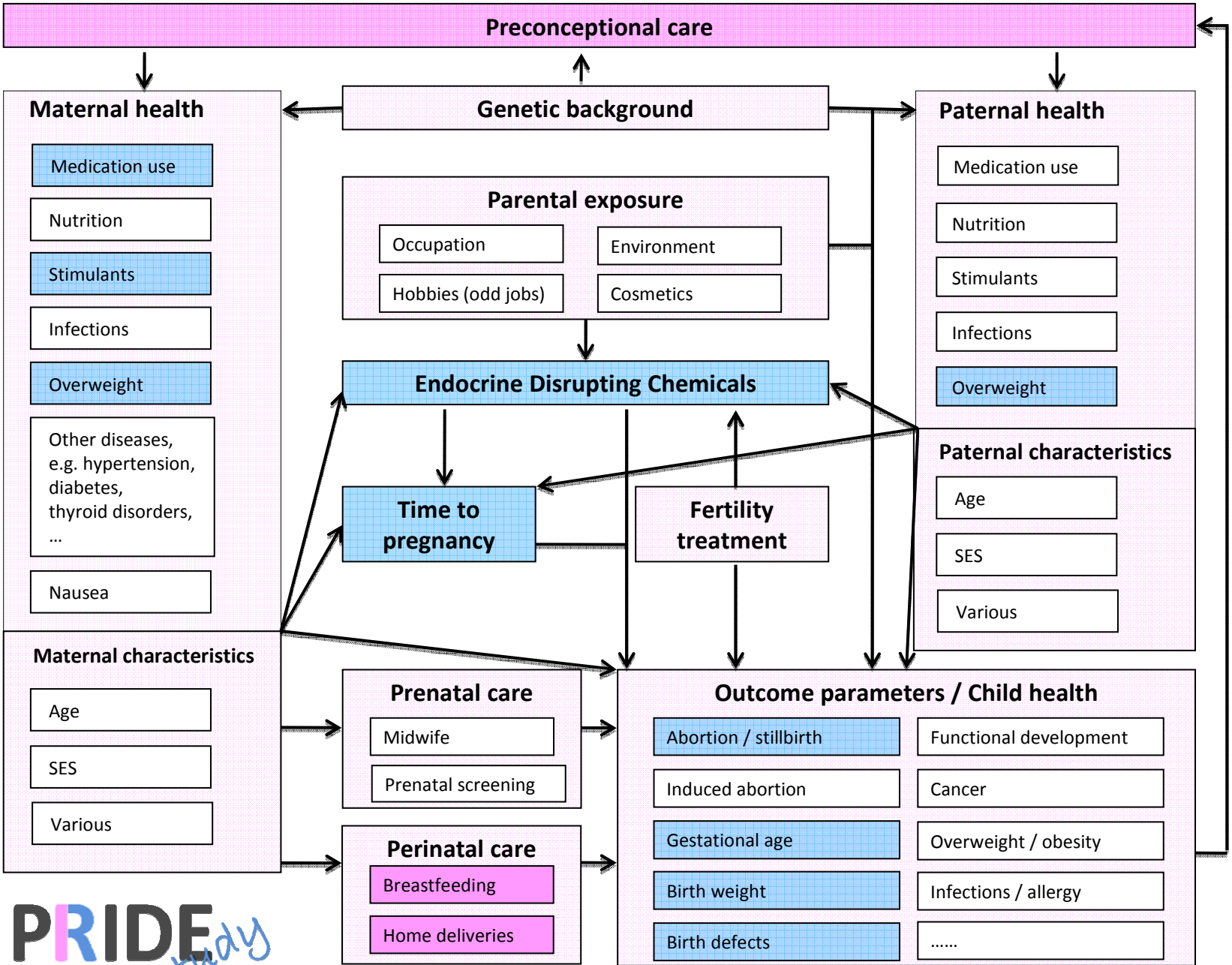
- Many possible research questions:
 - ✓ Who make use of preconception care ?
 - ✓ What is the most effective form of preconception care ?
 - Do women follow the advice given ?
 - Interventions ?
 - ✓ Does preconception care improve maternal and child health ?
- Major problem: preconception care will not be reimbursed before 2010

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Medication Use and Birth Defects in PRIDE Study

- PhD project: “Medical and recreational drugs during pregnancy and congenital malformations in offspring”
 - ✓ Funded by NWO Toptalent Grant 2007
- Literature study: Mechanisms of teratogenesis drugs
 - ✓ Theoretical basis
 - ✓ Classification of drugs in epidemiologic analyses, e.g.:
 - Folate antagonism
 - Vascular disruption
 - Oxidative stress